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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1636	17

DATE MAILED: 09/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,869	ANDERSON ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-86 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

I. Claims 1, 3, 5-13 and 14, drawn to an isolated nucleic acid molecule having at least 80% sequence identity or an isolated nucleic acid molecule that hybridizes to a nucleic acid molecule encoding an Mrg polypeptide having the recited SEQ ID NOs.; a vector, a host cell comprising the same and a method for producing a polypeptide using the same host cell, classified in class 536, subclass 23.5; class 435, subclasses 320.1, 69.1.

II. Claims 2, 4, 5-13 and 14, drawn to an isolated nucleic acid molecule having at least 80% sequence identity or an isolated nucleic acid molecule that hybridizes to a nucleic acid molecule encoding a drg-12 polypeptide having the recited SEQ ID NOs; a vector, a host cell comprising the same and a method for producing a polypeptide using the same host cell, classified in class in class 536, subclass 23.5; class 435, subclasses 320.1, 69.1.

III. Claims 15, 16, 18-20, 24 and 38-39, drawn to an isolated Mrg polypeptide, a chimeric molecule comprising an Mrg polypeptide, a composition and an

article of manufacture comprising an Mrg polypeptide, classified in class 530, subclass 350.

IV. Claims 15, 17, 21-23, 25 and 38-39, drawn to an isolated drg-12 polypeptide, a chimeric molecule comprising a drg-12 polypeptide, a composition and an article of manufacture comprising a drg-12 polypeptide, classified in class 530, subclass 350.

V. Claims 26-31 and 38-39, drawn to an isolated antibody that specifically binds to an isolated *Mrg* polypeptide of the presently claimed invention, a composition and an article of manufacture comprising the same, classified in class 424, subclass 139.1.

VI. Claims 32-37 and 38-39, drawn to an isolated antibody that specifically binds to an isolated drg-12 polypeptide of the presently claimed invention, a composition and an article of manufacture comprising the same, classified in class 424, subclass 139.1.

VII. Claims 40-42, drawn to a method for identifying Mrg expression in a sample using an anti-*Mrg* antibody, classified in class 435, subclass 7.1.

VIII. Claims 43-56, drawn to a method of identifying a compound that binds to an Mrg polypeptide by contacting a test compound with at least a portion of an Mrg polypeptide, classified in class 435, subclasses 7.1, 7.8.

IX. Claims 57-61, drawn to a method of identifying a molecule that binds to an Mrg polypeptide by contacting a host cell expressing an Mrg polypeptide with a test compound, classified in class 435, subclass 7.21.

X. Claims 62-64, drawn to a method of identifying a compound that binds to an Mrg polypeptide comprising contacting an Mrg polypeptide or fragment thereof with a test compound in the presence of a known ligand, classified in class 435, subclass 7.1.

XI. Claim 65, drawn to a method for identifying a compound that modulates expression of a nucleic acid moelcuele encoding an Mrg receptor, classified in class 435, subclass 4.

XII. Claims 66-74, drawn to a method for identifying an Mrg polypeptide agonist using a host cell known to be capable of producing a second messenger responses and expressing an Mrg polypeptide with a potential agonist, classified in class 435, subclass 4.

XIII. Claims 75-81, drawn to a method for identifying an Mrg polypeptide antagonist using a host cell known to be capable of producing a second messenger response and expressing an Mrg polypeptide with a known Mrg polypeptide agonist and a candidate antagonist, classified in class 435, subclass 4.

XIV. Claim 82, drawn to a method of identifying an Mrg polypeptide agonist antibody, classified in class 435, subclass 7.1.

XV. Claim 83, drawn to a method of identifying an Mrg polypeptide neutralizing an antibody, classified in class 435, subclass 7.1.

XVI. Claim 84, drawn to a transgenic non-human mammal with increased or decreased expression levels of an Mrg polypeptide, classified in class 800, subclass 14.

XVII. Claims 85-86, drawn to a method of treating impaired sensory perception in a mammal comprising administering to said mammal an agent that increases the expression of an isolated Mrg polypeptide can not be classified because the chemical structure of the agent is not specified.

Should Applicants elect the invention of Group I, further group restriction is required. Claims 1 and 3 contain a plurality of patentably distinct nucleic acid molecules encoding an Mrg polypeptide having the recited SEQ ID NOs. or having at least 80% sequence identity to nucleic acid molecules encoding an Mrg polypeptide having the recited SEQ ID NOs., that lack the unity of invention. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect one specific SEQ ID NO.

Should Applicants elect the invention of Group II, IV or VI, further group restriction is required. Claims 2, 15, 17 and 32 contain a plurality of patentably distinct nucleic acid molecules encoding a drg-12 polypeptide having the recited limitations with various SEQ ID NOs., isolated drg-12 polypeptides having the recited limitations with various SEQ ID NOs., isolated antibody specifically binds to the same that lack the unity of invention. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature

disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect one specific SEQ ID NO.

Should Applicants elect the invention of Group III or V or XVI or XVII, further group restriction is required. Claims 15, 16, 24, 26, 84 and 85 contain a plurality of patentably distinct isolated Mrg polypeptides having at least about 80% or about 40% sequence identity to the amino acid sequences having recited SEQ ID NOs, an isolated antibody that specifically binds to the same, a transgenic non-human mammal with increased or decreased expression levels of the same, and a method of treating impaired sensory perception in a mammal using an agent that increases the expression of the same, that lack the unity of invention. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect one specific SEQ ID NO.

Claims 38-39 contain a plurality of patentably distinct compositions of matter in a Markush form comprising: (a) an Mrg polypeptide; (b) a drg-12 polypeptide; (c) an anti-Mrg antibody, and (d) an anti drg-12 antibody, that lack the unity of invention. This is because there is no substantial common core structures or elements between the aforementioned compositions of matter. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect a specific composition of matter.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups I, II, III, IV, V, VI and XVI are unrelated. The isolated nucleic acid molecule having at least 80% sequence identity to a nucleic acid molecule that encodes an Mrg polypeptide having one of the recited SEQ ID NOs in Group I; the isolated nucleic acid molecule having at least 80% sequence identity to a nucleic acid molecule that encodes a drg-12 polypeptide having one of the recited SEQ ID NOs in Group II; the isolated Mrg polypeptide having the recited property in Group III; the isolated drg-12 polypeptide having the recited property in Group IV; the isolated antibody that binds to a Mrg polypeptide in Group V; the isolated antibody that binds to an isolated drg-12 polypeptide in Group VI; and the transgenic non-human mammal of Group XVI comprise chemically unrelated structures (e.g., unrelated and distinct amino acid and/or nucleotide sequences) capable of separate manufacture, use and effect.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because the methods in Groups VII to XV and XVII appear to constitute patentably distinct inventions for the following reasons: These methods are directed to methods that are distinct both physically and functionally, with different starting materials, method steps, desired end-results, as well as technical considerations for achieving these end-results. Additionally, these methods can be practiced independently one from the other. For examples, Group VII is drawn to a method for identifying Mrg expression in a sample using an anti-Mrg antibody; Group VIII is directed to a method of identifying a compound that binds to an Mrg polypeptide, and it is not required an anti-Mrg antibody; Group IX is drawn to a method

of identifying a molecule that binds to an Mrg polypeptide in a host cell; Group X is directed to a method of identifying a compound that binds an Mrg polypeptide in the presence of a known ligand under conditions where the binding of the known ligand is interferred; Group XI is directed to a method for identifying a compound that modulates expression of a nucleic acid encoding an Mrg receptor by measuring the differential expression of a reporter gene in the presence or absence of the tested compound; Group XII is drawn to a method for identifying an Mrg polypeptide agonist by measuring a second messenger response in a host cell known to be capable of producing a second messenger responses and expressing an Mrg polypeptide in the presence of a potential agonist; Group XIII is drawn to a method for identifying an Mrg antagonist using a host cell known to be capable of producing a second messenger response and expressing an Mrg polypeptide in the presence of a known Mrg polypeptide agonist and a candidate antagonist; Group XIV is directed to a method of identifying an Mrg polypeptide agonist antibody; Group XV is drawn to a method of identifying an Mrg polypeptide neutralizing antibody; and Group XVII is directed to a method of treating impaired sensory perception in a mammal utilizing an agent that increases the expression of an Mrg polypeptide of the presently claimed invention. Clearly, these methods have different method steps, starting materials, different desired end-results, and therefore different technical considerations for achieving the end-results.

The product of Group I is related to the method of Group XVII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used for producing the encoded polypeptide in cultured host cells. It is noted that the product of Group I is not required for the making or using of the processes in Groups VII to XVII.

The product of Group II is not required for the making or using of the processes in Groups VII to XV and XVII.

The product of Group III is related to the methods of Groups VIII, X, XIV, XV and XVII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group III can be used in any of the distinct aforementioned processes of Groups VIII, X, XIV, XV.

The product of Group IV is not required for the making or using of the processes in Groups VII to XV and XVII.

The product of Group V is related to the methods of Groups VII, XIV, and XV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In

the instant case the product of Group V can be used in any of the distinct aforementioned processes of Groups VII, XIV, and XV.

The product of Group VI is not required for the making or using of the processes in Groups VII to XV and XVII.

The transgenic non-human mammal of Group XVI is unrelated to the methods of Groups VII to XV and XVII, and therefore it is not required for the practice of any of these methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Additionally, due to the limited resources at USPTO, it would be unduly burdensome for searching the numerous SEQ ID NOs being recited in the claims in a single application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect Group V, claim 26 is generic to a plurality of disclosed patentably distinct species of isolated antibody comprising:

(a) monoclonal antibody; (b) antibody fragment; (c) humanized antibody; (d) agonist antibody; and (e) neutralizing antibody.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect Group VI, claim 32 is generic to a plurality of disclosed patentably distinct species of isolated antibody comprising:

(a) monoclonal antibody; (b) antibody fragment; (c) humanized antibody; (d) agonist antibody; and (e) neutralizing antibody.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect Group VIII, claims 43 and 49 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named test compound recited in the Markush group of claim 49.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER